NOV 2 1 2007

Topic: **SPECIAL 510K: for *change of VitaLogik 5000/5500 monitor***

510(k) Number: K073140
Establishment Name, Registration Number and Address:

Name:	Mennen Medical Ltd.
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Contact person:	Ifat Oren, Regulatory Affairs

The following information is being submitted in conformance with 21 CFR 807.87:

1. Classification Name	Detector And Alarm, Arrhythmia
2. Classification Number:	21 CFR 870.1025
3. Common/Usual Name	Physiological Patient Monitor
4. Trade/Proprietary Name	VitaLogik 4000/4500
7. FDA Classification	Class III
8. Product Code	DSI
9. Reviewing Panel	Cardiovascular
11. 510(k) Marketing clearance for VitaLogik	K052288 – December 20, 2005

Terminology

VitaLogik 4000/4500 = subject of this Special 510(k). The VitaLogik 4000/4500 is a modified device, of the VitaLogik 5000/5500 Patient Monitor

VitaLogik 5000/5500 Patient Monitor = the predicate device. The VitaLogik 5000/5500 was approved for marketing by the FDA (K052288 – 20 Dec. 2005)

Envoy Patient monitor = First device in the family. The Envoy was approved for marketing by the FDA

- K974510 – 14th April 1998
- K983864 – 8th October 1999
- K000563 – 17th May 2000
- K001120 – 8th May2001
- K011784 – 16th August 2001
- K022168 – 1st August 2002

The difference between the members of the monitor family is in their packaging.
The Envoy is a three unit monitor, the VitaLogik 5000/5500 has two units – Bed Side Computer and a stand alone display. The VitaLogik 4000/4500 is a one piece monitor with inbuilt display.

Subject of this special 510(k) = VitaLogik 4000/4500

Definition of Product Family: The VitaLogik 4000/4500 is a new member of the Envoy / VitaLogik family. As the other monitors it uses the same GUI and data storage capabilities. It can be viewed by the same Ensemble central nurse station and by the Enguard remote monitor. Data transfer and remote view is available between all members of the family.
The new VitaLogik 4000/4500 will measure, display and store the same vital signs as does the VitaLogik 5000/5500
It is offered in two basic options: VitaLogik 4000 – Non-Invasive monitor (the vital signs are ECG, NIBP, SpO2 and Temperature) and VitaLogik 4500 Full monitor (includes also two invasive Blood Pressures and Cardiac Output). Both have EtCO2 as an option.

Justification for Special 510(k) Submittal:

Based on the FDA Guidance Doc. (March 20, 1998) "The New 510(k) Paradigm" The evaluation of Regulatory Affairs (RA) of Mennen Medical Ltd. is that the changes made to the VitaLogik 5000/5500 to enable it to function as a *single unit* physiological patient monitor with an inbuilt display:

(i) do not affect the intended use of the VitaLogik 5000/5500
(ii) do not alter the fundamental scientific technology of the VitaLogik 5000/5500
(iii) do not affect the safety and efficacy of the VitaLogik 5000/5500
(iv) do not fall within the type of change that is inappropriate for a special 510(k) application.

Indication For Use

Device Name: **VitaLogik 4000/4500**

VitaLogik 4000/4500 is intended for use as a multiparameter physiological patient monitoring system.
The VitaLogik 4000/4500 can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure and EtCO2. This effectively allows the VitaLogik 4000/4500 to monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.
Functions include display of multiparameter waveforms, vital signs, alarm & status messages.
The Mennen Medical VitaLogik 4000/4500 is intended for sale as a system for monitoring and recording patient information or any in-hospital application requiring patient monitoring.
The following are examples of intended clinical applications:

- Critical Care Patients
- Cardiac Step-down/Telemetry Units
- Emergency Departments
- Intra-operative (Anesthesia) Monitoring
- Post Anesthesia Care

*The Intended Use of the VitaLogik 4000/4500 monitor as indicated above is the same as the Indications For Use.

Device Description: VitaLogik 4000/4500

The VitaLogik 4000/4500 is a configured multi-parameter physiological patient monitor, based on the hardware and software of the Mennen Medical VitaLogik 5000/5500 monitor, with integrated display screen. It is part of the Envoy/VitaLogik family and runs on same software versions.

In general, the VitaLogik 4000/4500 has the same functions, intended use and technology as the VitaLogik 5000/5550, the main different between the VitaLogik 4000/4500 and the VitaLogik 5000/5500 is the addition of battery power supply that gives the VitaLogik 4000/4500 same abilities as the VitaLogik 5000/5500 with the ability to use it as a transport monitor. To reduce the power consumption we have also replaced the hard disc memory with a Compact Flash memory.

The VitaLogik 4000/4500 uses identical display and patient data as do the VitaLogik 5000/5500 and Envoy monitors. The Ensemble central station and the Enguard remote monitor can both view the VitaLogik 4000/4500, VitaLogik 5000/ 5500 as well as the Envoy.

The VitaLogik 4000/4500 bedside patient monitor consists of a main processing unit, and an integrated color monitor with optional touch screen.

The front end electronic has same hardware and software as VitaLogik 5000/5500 . The input connectors are incorporated in the side panel of the monitor.

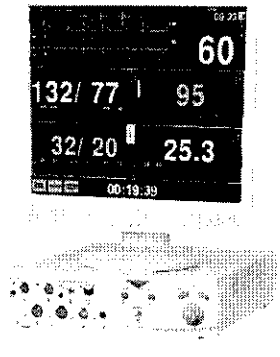
The VitaLogik 4000/4500 monitor presents vital signs in the same way and the same GUI (Graphic User Interface) as does the VitaLogic 5000/5500 monitor.

The VitaLogik 4000/4500 can acquire the following physiological signals of the patient:

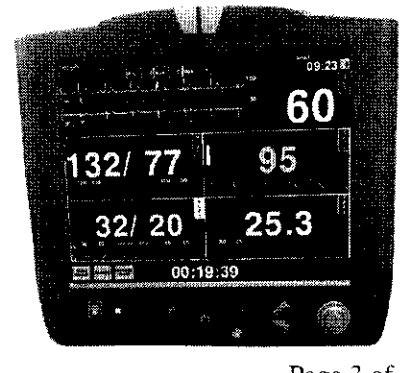
- ECG – Waveform and measures Heart Rate, ST and Arrhythmia
- Blood Pressures – Waveform and measures Systole, Diastole and Mean Pressure
- Temperature – As a numeric value in C° or F°
- SpO2 – Photoplethysmographic waveform and numeric value of the oxygen saturation and pulse rate
- NIBP – Systolic, Diastolic and Mean pressure with measuring time stamp
  EtCO2 – EtCO2, inCO2 and Respiration Rate

Substantial Equivalence: Comparison: **VitaLogik 4000/4500** with **VitaLogik 5000/5500**

VitaLogik 5000/5500 Photo



VitaLogik 4000/4500 Photos



The major differences between the VitaLogik 4000/4500 and the VitaLogik 5000/5500 are:

1. The VitaLogik 4000/4500 works also on battery
2. The VitaLogik 4000/4500 has integrated display and is thus a one piece monitor, as compared to VitaLogik 5000/5500 that has a stand alone display
3. The input connectors of the VitaLogik 4000/4500 are on the side of the monitor, as compared to connectors on the front for the predicated device VitaLogik 5000/5500
4. The VitaLogik 4000/4500 user a Compact Flash memory instead of a hard disc in VitaLogik 5000/5500

The following table compares the major software element and/or changes done in the VitaLogik 4000/4500 vs. the VitaLogik 5000/5500:

SW Component	**VitaLogik 5000/5500**	**VitaLogik 4000/4500**
Display	All waveforms and numeric vital sings	Same
Operating System	QNX4	Same
GUI	Same	Same
Menus	Full set	Same
Vital signs	Depend on model: 5000 – Non invasive 5500 - Invasive	Same

We consider the VitaLogik 4000/4500 to be substantially equivalent to the VitaLogik 5000/5500 monitor and we submit that any differences between the two systems

- fall within the scope of a Special 510(k) Device Modification and
- do not raise any new issues of safety and effectiveness

Confidentiality

Mennen Medical Ltd. considers its intent to market the VitaLogik 4000/4500 System to be confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising and law firms, and its consultants. The Company, therefore, requests the FDA not disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

Signature:

Ifat Oren

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 2 1 2007

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Rehovot
ISRAEL 76100

Re: K073140
VitaLogik Model 4000/4500
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: Class II (two)
Product Code: DSI
Dated: November 1, 2007
Received: November 7, 2007

Dear Mr. Oren:

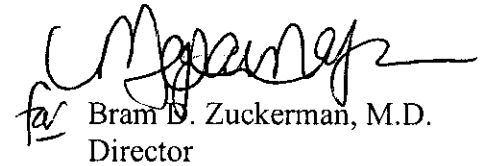
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073140

Device Name: **VitaLogik 4000/4500**

Indications For Use:

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*The Intended Use of the Envoy monitor as indicated above is same as the Indications For Use.

Prescription Use _YES_ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073140